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EXAMINER

GORDON, BRIAN R

ART UNIT PAPER NUMBER

1743

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/875,184

Applicant(s)

TAKII ET AL.

Examiner

Brian R. Gordon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Response to Arguments***

2. Applicant's arguments filed November 1, 2005 have been fully considered but they are not persuasive.

As to claim 1, the 103 rejection of claim 1 over Tyberg in view of Shalon et al. is hereby withdrawn. However, Tyberg et al. in view of Beinert is maintained for plate 240 through which the probes slide may also be considered an equivalent to the claimed guide.

As to applicant's argument's as directed to the 103 rejection of claim 3, the examiner asserts the comments as directed to Ade are clear. Claim 3 does not specifically state the location of the buffer tank as being between elements. In anticipation of such an amendment to specify such, the examiner cited Ade as to show a buffer tank (diluent tank) may be located within an aspiration system at a different position other than that as disclosed by Schultz. The claim only requires that the suction pump be connected to the buffer tank. The examiner asserts the suction pumps of Schultz are connected to the buffer tank 50 via connecting elements. The manifold of the device of Schultz is clearly pointed out as indicated in parenthesis below. Schultz also comprises a switching valve 30 equivalent to that as claimed (column 4 beginning at line 3).

The rejection of claim 4 is also maintained in view of the reasons as applied to claims 1 and 3 above.

Clarity issues remain present in the claims. The examiner previously suggested language to overcome some of the issues. Applicant chose not to adapt all of the changes, hence the issues remain as given below.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant states the buffer tank is located between the suction pump and the branch manifold (remarks page 10), the claims do not specify such. The buffer tank is only recited as being connected to the suction pump. There is no mention of the buffer tank being connected to the manifold. The claim does not preclude the suction pump from being connected to the buffer tank and manifold in a parallel a parallel configuration rather than series. However, the specification only discloses the elements as being connected in series.

Furthermore it is unclear what is sucked from the nozzles. The examiner suggest applicant adopt the previous suggestion which stated the solution is sucked from the nozzles and through the manifold.

How can the liquid in the vessel be sucked from simultaneously from the nozzles? The liquid must first be established as being present in the nozzles. The liquid in the vessel simultaneously through the nozzles.

The claims also uses the term "another" in referencing the two ports. The examiner suggests using the term "second" or "other" port.

It is unclear if the liquid filling occurs with solution from the vessel or another liquid. It appears as if the liquid filling occurs with a solution from the liquid conveying means. As such, to clarify such the examiner suggests amending the claims as given below.

The examiner suggests amending the claims as given below to overcome the 112 rejections given herein.

Claim 3 (Currently amended): A drainage system comprising:

a buffer tank;

a plurality of suction nozzles for sucking and discharging a solution from a vessel',

a branch manifold connected to the suction nozzles through pipes;

a suction pump connected to said buffer tank for suction of the solution from the suction nozzles through the branch manifold; and

liquid conveying means for feeding a liquid through said manifold and into the pipes located between the branch manifold and each of the suction nozzles, thereby filling the pipes with the liquid; and

a switching valve directly connected to each of the buffet tank, liquid conveying means, and the branch manifold,

the suction pump being capable of operating so that the solution in the vessel can be sucked out simultaneously ~~from~~ through the suction nozzles then through the branch manifold,

wherein the buffer tank has two ports, one port is directly connected to the suction pump and ~~another~~ said second port is directly connected to the switching valve,

wherein said switching valve allows for liquid filling of said pipes via said liquid conveying means when in a first position and suction of the solution from said vessel when in a second a position.

Claim 4 (Currently Amended): A drainage system comprising:

a plurality of suction nozzles for sucking and discharging a solution from a vessel;

support means for supporting the suction nozzles for movement toward the vessel;

suction nozzle moving means including urging means for urging the suction nozzles toward the vessel and a guide, located beneath the urging means, for slidably supporting the plurality of suction nozzles;

suction nozzle;

a magnet;

magnet moving means for supporting the magnet so as to be movable toward and away from the vessel;

a buffer tank;

a branch manifold connected to the suction nozzles through pipes; a suction pump connected to said buffer tank for suction from the suction nozzles through the branch manifold; and

liquid conveying means for feeding a liquid through said manifold and into the pipes located between the branch manifold and each of the suction nozzles, thereby filling the pipes with the liquid; and

a switching valve directly connected to each of said manifold, liquid conveying means, and buffer tank;

the suction nozzle moving means being capable of positioning the suction nozzle with the distal end thereof in contact with the inner wall surface of the vessel,

the magnet being capable of holding magnetic particles in a given position in the vessel by being moved toward the vessel by the magnet moving means, and

the suction pump being capable of operating so that the solution in the vessel can be sucked out simultaneously ~~from~~ through the suction nozzles then through the branch manifold, and

wherein said switching valve allows for liquid filling of said pipes via said liquid conveying means when in a first position and suction of the solution from said vessel when in a second a position.

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tyberg et al. US 6,270,726 in view of Beinert et al., WO 00/08474.

Tyberg discloses a pipetting station having a bottom sensing device is provided in conjunction with one of any known liquid level sensing devices. The bottom sensing

device includes a pipetting probe **spring** mounted to a pipetting arm of the pipetting station. The bottom sensing device also includes a sensor for determining when a pipetting tip of the pipetting probe is in contact with a bottom of a tube. The bottom sensing device permits the pipetting probe to measure an exact volume of fluid in the tube by allowing the pipetting tip (suction nozzle) to be lowered to the bottom of the tube beyond the sensed fluid level.

The pipetting station 24 (moving means) includes the pipetting arm 32 (support means) that moves in the direction of arrow 42, and a pipetting probe 34 **spring** mounted to the pipetting arm 32 of the pipetting station 24. The pipetting probe 34 includes a pipetting tip 36 having a capacitive level sensor as described with reference to U.S. Pat. No. 5,648,727. The capacitive sensor senses a level of the fluid and determines that level in relation to a known "home" position. The tube 20 is placed in a holding device (see FIG. 4) so that a bottom of the tube 20 is at the reference line "X" which is used as a reference point for discussion purposes only.

Tyberg does not disclose a guide located beneath the urging means.

Beinert et al. disclose a freely traversable metering head with numerous metering devices, wherein the metering devices are each provided individually or block-by-block with an activating device, and wherein a controller traversable with the metering head is designed for the independent operation of one or more activating devices.

The metering head with the micropipette matrix is provided with a **guide** on the mounting block, so that, when the respective actuating element is operated, the corresponding micropipette is first moved from a retracted basic position to a projecting

pipetting position relative to the mounting block before the pipetting volume changes. For the first time, a metering head is provided thereby in which, as with the projecting picking needles, micropipettes are selectively moved into the pipetting position and activated individually or simultaneously in a freely addressable manner.

The invention also relates to the combination of a micropipette that exhibits a cylinder, a pipette tip and a pipette piston, which is biased relative to the cylinder by means of a pin spring, with a carrier or mount that allows the micropipette to be moved relative to the carrier parallel to the longitudinal direction of the pipette. The cylinder of the micropipette is biased relative to the carrier with a cylinder spring. The micropipette is moved relative to the carrier between two end positions via the maximal expansion or maximal compression of the cylinder spring.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Tyberg by providing a guide/mounting block as that taught by Beinert to ensure the vertical orientation of the pipette is maintained during operation.

5. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. in view of Ade et al. US 5,853,665.

Schultz et al. discloses an automated assaying system is disclosed having a multiplicity of lumens oriented and controllable in clusters. The lumens are portrayed in a matrix, wherein each row of the matrix consists of one such cluster that is individually controllable for aspiration and dispensation purposes. Also provided is a unique wash

system capable of flushing the entirety of the system. A method is also depicted for accomplishing this unique assaying.

The device a hydraulic solution source 50 (buffer tank) which may contain any acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, a pump 12 (liquid conveying means) is thereafter connected thereto. Pump 12 is preferably of the peristaltic type, however, any fluid-type pump may be employed. From pump 12, a conduit 14 consisting of branch tubing coupled to, in this case, as depicted, two valves 16. The distribution valves 16 channel the wash fluid into a plurality of controllable cells 32. For example, as depicted, the distribution valves 16 provide output lines as arterial tubing 18 in equal numbers of six which spread to 12 of the housings 32 (manifold) via a valve 30 on each housing 32.

Syringes 52 (suction pump), of course, contain plungers 54 on plunger shafts 82. As there are eight syringes depicted in FIGS. 3 and 4, with four being to the front of the unit and four being to the rear, a plunger-pushing base 62 couples all of the syringe plunger shafts 82 together in any given unit. A motor 72, also coupled to a computer system, may specifically meter volumes via the syringes 52, either positively or negatively. That is, the plungers 54 may be pushed up to force fluid out of the system, or the plungers 54 may be drawn down to suction fluid into the system, both through probes 26 (suction nozzles).

As can be seen in FIGS. 4 through 6, the top spider ports 64 and the bottom spider ports 66 are slightly offset. This slight offset allows for the 180 degree rotation of an internal shaft 80 which acts as a valve key sleeve within an outer sleeve 78. That

valve key sleeve 80, as depicted in FIGS. 5 and 6, contains, importantly, two grooves 74. While in an open position, those grooves orient with the spider ports 56. However, when those grooves 74 are rotated 180 degrees, they no longer align with the spider ports 56, but instead a solid portion of the key sleeve 80 orients with those ports, closing them off from the wash system downstream. Therefore, when in a closed position, the system is controllable only by syringes 52 via motors 72, but not by pump 12. Importantly, each motor 72 may be individually controlled. Therefore, as depicted in FIG. 1, each of the twelve syringe housings 32, containing eight syringes and output ports, are individually controllable via a motor 72.

Thereafter, the lumens 34 extending from tips 60 are arranged as ganged clusters within tubing management housing 20. Tubing management housing 20 is preferably a flexible tract housing. Oriented with tubing management housing 20 is a swivel 48. Swivel 48 allows the upper portion of the tubing management housing 20 to slightly disorient or skew itself without binding of the lumens contained therein. That is, as tubing management housing 20 is moved about, swivel 48 allows that portion of tubing management housing 20 above swivel 48 to swivel freely so as not to foul. Tubing management housing 20 is also coupled to a three-dimensional robotic arm system (suction nozzle moving means), consisting of a vertical motion shaft 36, lateral motion couple 38 and longitudinal motion sleeve 40. The vertical motion shaft 36 is coupled at an upper portion to the management tubing 20, slightly below the swivel 48, and then at a lower portion to a U-shaped bracket 46 (support means).

Shultz discloses the employment of a buffer tank (50) that supplies acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, but does not disclose the buffer tank being located between the suction pump and the branch manifold.

Ade et al. discloses an apparatus for transferring fluid samples such as blood from containers. The apparatus includes an aspiration head that is connected to a vacuum pump. The system also comprises a diluent supply (buffer tank) located the pump and the point of aspiration between (implication of two ports for communication with both pump and aspiration point). After aspiration of a sample is complete, diluent solution (i.e. backwash solution) is selectively applied to the aspiration line through a solenoid-controlled valve LV2 (switching valve) located in a diluent supply line 40. The flushing of diluent solution cleanses and prepares the aspiration line and needle for aspiration of subsequent blood samples.

As previously stated Shultz does disclose a buffer tank however, it would have been obvious to one of ordinary skill in the art to recognize that the location of the tank may be located at a point between the pump and the manifold as taught by Ade et al. to flush and wash the plumbing system between aspiration cycles.

6. Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al. in view Tyberg et al. in view of Beinert et al. (as applied to claim 1 above) and further in view of Yu US 5,779,907.

Schultz et al. discloses an automated assaying system is disclosed having a multiplicity of lumens oriented and controllable in clusters. The lumens are portrayed in

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a matrix, wherein each row of the matrix consists of one such cluster that is individually controllable for aspiration and dispensation purposes. Also provided is a unique wash system capable of flushing the entirety of the system. A method is also depicted for accomplishing this unique assaying.

The device a hydraulic solution source 50 (buffer tank) which may contain any acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution, a pump 12 (liquid conveying means) is thereafter connected thereto. Pump 12 is preferably of the peristaltic type, however, any fluid-type pump may be employed. From pump 12, a conduit 14 consisting of branch tubing coupled to, in this case, as depicted, two valves 16. The distribution valves 16 channel the wash fluid into a plurality of controllable cells 32. For example, as depicted, the distribution valves 16 provide output lines as arterial tubing 18 in equal numbers of six which spread to 12 of the housings 32 (manifold) via a valve 30 on each housing 32.

Syringes 52 (suction pump), of course, contain plungers 54 on plunger shafts 82. As there are eight syringes depicted in FIGS. 3 and 4, with four being to the front of the unit and four being to the rear, a plunger-pushing base 62 couples all of the syringe plunger shafts 82 together in any given unit. A motor 72, also coupled to a computer system, may specifically meter volumes via the syringes 52, either positively or negatively. That is, the plungers 54 may be pushed up to force fluid out of the system, or the plungers 54 may be drawn down to suction fluid into the system, both through probes 26 (suction nozzles).

As can be seen in FIGS. 4 through 6, the top spider ports 64 and the bottom spider ports 66 are slightly offset. This slight offset allows for the 180 degree rotation of an internal shaft 80 which acts as a valve key sleeve within an outer sleeve 78. That valve key sleeve 80, as depicted in FIGS. 5 and 6, contains, importantly, two grooves 74. While in an open position, those grooves orient with the spider ports 56. However, when those grooves 74 are rotated 180 degrees, they no longer align with the spider ports 56, but instead a solid portion of the key sleeve 80 orients with those ports, closing them off from the wash system downstream. Therefore, when in a closed position, the system is controllable only by syringes 52 via motors 72, but not by pump 12. Importantly, each motor 72 may be individually controlled. Therefore, as depicted in FIG. 1, each of the twelve syringe housings 32, containing eight syringes and output ports, are individually controllable via a motor 72.

Thereafter, the lumens 34 extending from tips 60 are arranged as ganged clusters within tubing management housing 20. Tubing management housing 20 is preferably a flexible tract housing. Oriented with tubing management housing 20 is a swivel 48. Swivel 48 allows the upper portion of the tubing management housing 20 to slightly disorient or skew itself without binding of the lumens contained therein. That is, as tubing management housing 20 is moved about, swivel 48 allows that portion of tubing management housing 20 above swivel 48 to swivel freely so as not to foul. Tubing management housing 20 is also coupled to a three-dimensional robotic arm system (suction nozzle moving means), consisting of a vertical motion shaft 36, lateral motion couple 38 and longitudinal motion sleeve 40. The vertical motion shaft 36 is

coupled at an upper portion to the management tubing 20, slightly below the swivel 48, and then at a lower portion to a U-shaped bracket 46 (support means).

Shultz discloses the employment of a buffer tank (50) that supplies acceptable hydraulic solution, including water, sterile saline, solvent, or some other washing solution.

Schultz does not teach a device that comprises nozzle moving including urging means for urging the suction nozzles toward the vessel, magnet, and a magnet moving means.

Tyberg in view of Beinert (as given above) discloses a pipetting station 24 (moving means) includes the pipetting arm 32 (support means) that moves in the direction of arrow 42, and a pipetting probe 34 **spring** (urging means) mounted to the pipetting arm 32 of the pipetting station 24. The pipetting probe 34 includes a pipetting tip 36 having a capacitive level sensor as described with reference to U.S. Pat. No. 5,648,727. The capacitive sensor senses a level of the fluid and determines that level in relation to a known "home" position. The tube 20 is placed in a holding device (see FIG. 4) so that a bottom of the tube 20 is at the reference line "X" which is used as a reference point for discussion purposes only. As taught above it would have been obvious to modify the device of Tyberg to include a configuration of the block of Beinert which includes a guide to ensure vertical alignment of the pipette is maintained.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Schultz et al. by employing the sensing system of the modified device of Tyberg in order to prevent the probes 26 of the device of Schultz

from breaking in the event that the robotic system moves the probes down to far to contact the basin 28.

Yu a magnetic microplate separator for use with a microplate provided with multiple wells for containing liquid under analysis, comprising a support plate, and a plurality of magnets supported on the support plate and extending upwardly into the spaces formed between the wells of the microplate from underneath the microplate.

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the modified device of Schultz et al. by incorporating the automated magnetic system of Yu to allow for automated process of separating unwanted particles from the fluid to be aspirated.

#### ***Allowable Subject Matter***

5. Claim 2 is allowed.
6. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record (Yu) does not teach nor fairly suggest the specific magnetic moving means comprising a spring interposed between two support plates as claimed in combination with the other elements of claim 2.

#### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1700.

brg  
January 3, 2006

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700